REMARKS

The Office Action

In the Office Action mailed March 13, 2007, the Examiner objected to an informality in the specification and noted that two claims numbered as "19" had been submitted in the application. Additionally, the Examiner rejected claims 1-43 under 35 U.S.C. 101 as being directed to non-statutory matter. The Examiner also rejected claims 1-9, 12-33, and 38-39 under 35 U.S.C. 102(b) as being anticipated by DiGioia, III et al., U.S. Patent No. 6,205,411 (hereinafter "DiGioia"). Claims 10 and 11 were rejected under 35 U.S.C. 103(a) as being unpatentable over DiGioia in view of Ella, U.S. Publ. No. 2004/0071637 (hereinafter "Ella"). For reasons set forth in detail below, Applicants submit that the amended claims overcome these objections and grounds of rejection.

Objections

The objection to the specification informality has been addressed by the replacement paragraph presented above. The amended paragraph removes "method system" and replaces it with "method." Applicants submit that this amendment addresses the objection. With regard to the additional claim 19, Applicants moved it to the end of the claim listing and identified the claim as new claim 44. A check covering the examination of this claim is also provided with this amendment. Applicants submit that this change in the claim listing addresses the claim objections.

Section 101 Ground of Rejection

The Examiner has rejected claims 1-43 as failing to be directed to statutory subject matter. The subsystems set forth in the claims are described as computer programs executing on computer systems. Exemplary computers are identified in the specification along with interfaces for communicating image data with CT, MRI, and other image sources as well as displays for generated images. *Specification*, page 18, lines 1-14. Thus, claims 1 and 32 set forth elements having hardware components by reciting the anthropometric data analyzer, implant model generator, and kinematic model simulator, and motion data analyzer. These elements modify and display data signals and, therefore,

constitute statutory subject matter. Nevertheless, Applicants have amended the claims to include a database for storing the dynamic response data generated by the kinematic model simulator. Applicants submit that claims 1 and 32 as well as claims 2-17 and 33-37 that depend from them, respectively, are directed to statutory subject matter.

With regard to the method claims, Applicants submit that the generation of implant model data and dynamic response data, at least, require hardware and result in data modification that alters the fabrication of implants. These claims, however, have also been amended to include the storage of the dynamic response data in a computer memory, such as a database. Therefore, Applicants submit that claim 18 and its dependent claims 19-31 plus new claim 44 and claim 38 and its dependent claims 39-43 are all directed to statutory subject matter.

The title of the application indicates that the system and method disclosed and claimed in the specification achieve the goal of designing a physiometric system. The claimed systems and methods generate an initial implant model for a group of joints, generate a simulation that produces data indicative of the range of motion of the implant corresponding to the implant model, detect conditional data indicative of range of motion problems, and generate data for modifying the implant model to attenuate the range of motion problems. The systems and methods provide iterative feedback and have a stopping criterion for selecting a best implant model, which is used to fabricate an implant. The design data for the implant is output by the systems and methods described in the application and are extremely useful for the production of implants that cover a range of patients. For at least these reasons, Applicants submit that all pending claims 1-44 are directed to statutory subject matter.

Section 102 Ground of Rejection

In support of the 102 ground of rejection, the Examine has cited DiGioia as disclosing an anthropometric data analyzer, an implant model generator, and a kinematic model simulator. The system of DiGioia, however, is limited to a single patient's joint. As taught in DiGioia, *the* skeletal structure is obtained from the skeletal data source.

DiGioia, col. 6, lines 49-54. The tomographic data from *the* scanned structure generated by the skeletal data source is provided to the geometric planner to produce a model of *the* skeletal structure. *DiGioia*, col. 6, lines 58-61. The models of the joint and the artificial component are used to simulate movement of *the* joint that will contain the artifical components. *DiGioia*, col. 7, lines 19-22. Variations in the testing are performed to optimize size, position, and orientation of the artificial components in *the* patient's joint. *DiGioia*, col. 7, lines 22-27. Thus, DiGioia only teaches that image data of a single joint are used with artificial joint models to construct an optimized implant for a single patient.

Applicants' have developed a system that avoids the customization and one-of-a-kind implant production that occurs with use of the system in DiGioia. Applicants have noted that this level of customization is too expensive and resource intensive. *Specification*, page 2, lines 7-11. While the variations in human anatomy present formidable obstacles to produce implants that meet the needs for a range of patients, *Specification*, page 2, line 12 to page 3, line 4, Applicants have developed a system that analyzes image data for a plurality of joints in a group of patients to generate an implant model that may be used to fabricate a single version of an implant that meets the needs of all. The system of DiGioia cannot produce such an implant and that is why Applicants' invention is patentable over previously known systems.

Claim 1

Claim 1 has been amended to include the limitation that the anthropometric analyzer receives data representative of a plurality of joint in a plurality of subjects and that the received data are analyzed to identify a plurality of geometric dimensions with a range of values for the dimensions. DiGioia does not teach or suggest such an analyzer as it only analyzes the image data of a single joint in a single patient. Likewise, amended claim 1 requires the implant model generator to receive the geometric dimensions and range of values produced by the anthropometric analyzer and to generate a set of model data representative of the received data. Even if the implant model generator generates more than one model, each model is representative of a group of joints in multiple patients. The implant model of DiGioia is only representative of a single joint in a single patient.

Consequently, DiGioia does not teach or suggest the system of claim 1 and, Applicants submit the claim is allowable.

Claim 2

Claim 2 includes a dynamic response data analyzer that generates differential dimensional data. The Examiner has stated that DiGioia discloses the generation of differential data. Applicants have reviewed the cited portions of DiGioia. While there is a brief discussion that data are used for optimization of size, position, and orientation of artificial components, there is no reference to the method used for this optimization. Thus, DiGioia does not expressly teach the generation of differential dimensional data from dynamic response data. For at least this reason, claim 2 is allowable over all references of record, either alone or in combination.

Claim 3

Claim 3 requires the implant model generator to incorporate differential dimensional data in the generation of a second set of model data. The Examiner has stated that DiGioia discloses an implant model generator that performs this function. Applicants have reviewed the cited portions of DiGioia and do not see any specific references to the incorporation of differential dimensional data in a second set of model data. DiGioia certainly does not teach or suggest the incorporation of differential dimensional data in an implant model that is representative of a plurality of joints. Thus, DiGioia does not expressly teach the limitations of claim 3. For at least this reason, claim 3 is allowable over all references of record, either alone or in combination.

Claim 4

Claim 4 includes the limitations of claims 2 and 1. Therefore, it is patentable for the reasons set forth above with respect to those claims.

Claims 5 and 6

Claims 5 and 6, as amended, require a CT or MRI image data source to provide data for a plurality of joint for a plurality of patients. As already noted, DiGioia fails to teach or

suggest such a limitation because it is a system that customizes an implant for a single patient. Consequently, these claims are allowable over the references of record, either alone or in combination.

Claims 7 and 8

Claims 7 and 8 include the limitations of claim 1. Therefore, they are patentable for the reasons set forth above with respect to claim 1.

Claim 9

Claim 9 requires the static image data analyzer to be an adaptation of a computer program that measures terrain topographic features. "Terrain" refers to geographical features. DiGioia refers only to a disclosure of a technique for three dimensional modeling of human organs. Human organs are very different than geographical terrain in scope and techniques for measurement and analysis. Therefore, claim 9 is neither taught nor suggested by any references of record, either alone or in combination.

Claims 10-16

Although claims 12-16 were rejected under 35 U.S.C. 102(b), claims 12 and 14-16 depend directly or indirectly from claim 10 and/or 11. Claims 10 and 11 were rejected under 35 U.S.C. 103(a). Therefore, Applicants conclude that claims 12 and 14-16 were also rejected under 35 U.S.C. 103(a). These claims are addressed below in the 103 ground of rejection section. Claim 13 has been amended to depend from claim 12 and, therefore, it is discussed below with these claims.

Claim 17

Claim 17 requires a motion data analyzer for analyzing joint motion image data studies to group the studies into sets correlated by the degree of motion demonstrated during a particular activity. The Examiner cites portions of DiGioia and assets that DiGioia teaches such a motion data analyzer. Applicants respectfully disagree. The word "studies" refers to images of a plurality of joints. Claim 17 has been amended to make

this aspect explicit. Because DiGioia is directed to analysis of a single joint only, claim 17 is allowable over all references of record, either alone or in combination.

Claim 18

Claim 18 has been amended to specify the image data are analyzed for a plurality of joints. Therefore, claim 18 is patentable over all references of record, either alone or in combination, for reasons similar to those express above with respect to claim 1.

Claim 19

Claim 19 depends from claim 18 and is at least patentable for reasons discussed above with respect to that claim. Additionally, claim 19 requires the generation of differential dimensional data for the modification of a set of model data representative of a plurality of joints. Therefore, for reasons similar to those set forth above with respect to claim 2, claim 19 is patentable over all references of record, either alone or in combination.

Claim 20

Claim 20 depends from claims 19 and 18 and is at least patentable for reasons discussed above with respect to those claims. Additionally, claim 20 requires a determination whether a set of model data that is representative of a plurality of joints meets an acceptance parameter. Therefore, for reasons similar to those discussed above with respect to claims 1 and 18, claim 20 is patentable over all references of record, either alone or in combination.

Claims 21 and 22

Claims 21 and 22 depend from claim 18 and are at least patentable for reasons discussed above with respect to that claim. Additionally, claims 21 and 22 require that the CT and MRI data sources provide images for a plurality of joints. Therefore, these claims are patentable for reasons similar to those set forth above with respect to claims 5 and 6.

Claims 23-24 and 26-30

Claims 23-24 and 26-30 depend from claim 18 and are at least patentable for reasons discussed above with respect to that claim.

Claim 25

Claim 25 depends from claim 23 and is at least patentable for reasons discussed above with respect to claims 23 and 18. Additionally, claim 25 requires the three dimensional data analysis to include use of a computer program that measures terrain topographic features. DiGioia does not teach or suggest any use of a terrain topographic feature measurement program. Thus, it is also patentable for reasons similar to those set forth above with respect to claim 9.

Claim 31

Claim 31 depends from claim 29 and is at least patentable for reasons discussed above with respect to claims 29 and 18. Additionally, claim 31 requires that the dynamic response data analysis include generating differential dimensional data for alteration of model data representative of a plurality of joints. DiGioia cannot teach or suggest such a limitation as it is only directed to analysis of a single joint for a single patient. Therefore, claim 31 is patentable over all references of record, either alone or in combination.

Claim 32

Claim 32 has been amended to specify the image data analyzed is for a plurality of joints. Therefore, claim 32 is patentable over all references of record, either alone or in combination, for reasons similar to those express above with respect to claims 1 and 18. Claim 32 also includes a motion data analyzer that analyzes joint motion image data for a plurality of joints. Thus, it is also patentable for reasons similar to those set forth above with respect to claim 17.

Claims 33 and 36-37

Claims 33 and 36-37 depend from claim 32 and are at least patentable for reasons discussed above with respect to that claim.

Claim 34

Claim 34 depends from claim 32 and is at least patentable for reasons discussed above with respect to that claim. Additionally, claim 34 requires the motion data analyzer to perform frequency distribution analysis on joint motion image data for a plurality of joints. As DiGioia is only directed to analysis of a single joint for a single patient, claim 32 is not anticipated by this reference. Because no other reference, either alone or in combination, teaches or suggests such frequency distribution analysis, claim 34 is also patentable.

Claim 35

Claim 35 depends from claim 34 and is at least patentable for reasons discussed above with respect to claims 34 and 32. Additionally, claim 35 requires the anthropometric data analyzer to determine whether one or more geometric dimension groupings correlate to the *joints* depicted in the image studies that are associated with a motion grouping. As DiGioia is only directed to analysis of a single joint for a single patient, claim 35 is not anticipated by this reference. Because no other reference, either alone or in combination, teaches or suggests such frequency distribution analysis, claim 35 is also patentable

Claim 38

Claim 38 has been amended to specify the joint motion image data are analyzed for a plurality of joints. Therefore, claim 38 is patentable over all references of record, either alone or in combination, for reasons similar to those express above with respect to claims 1, 18, and 32.

Claim 39

Claim 39 depends from claim 38 and is at least patentable for reasons discussed above with respect to that claim.

Claim 40

Claim 40 depends from claim 38 and is at least patentable for reasons discussed above with respect to that claim. Additionally, claim 40 requires frequency distribution analysis on joint motion image data for a plurality of joints. As DiGioia is only directed to analysis of a single joint for a single patient, claim 40 is not anticipated by this reference. Because no other reference, either alone or in combination, teaches or suggests such frequency distribution analysis, claim 40 is also patentable.

Claim 41

Claim 41 depends from claim 40 and is at least patentable for reasons discussed above with respect to claims 40 and 38. Additionally, claim 41 requires the analysis of anthropometric data to determine whether one or more geometric dimension groupings correlate to the *joints* depicted in the image studies that are associated with a motion grouping. As DiGioia is only directed to analysis of a single joint for a single patient, claim 41 is not anticipated by this reference. Because no other reference, either alone or in combination, teaches or suggests such frequency distribution analysis, claim 41 is also patentable.

Claims 42-43

Claims 42-43 depend from claim 41 and are at least patentable for reasons discussed above with respect to claims 41, 40, and 38.

Section 103 Ground of Rejection

Claims 10 and 11 were rejected under 35 U.S.C. 103(a) as being unpatentable over DiGioia in view of Ella. Claims 12-16 depend from claim 10. Therefore, all of these claims require the patient model emulator set forth in claim 10. As the Examiner has admitted that DiGioia does not teach a patient emulator, none of these claims can be anticipated by DiGioia. The combination of DiGioia and Ella is now discussed with reference to these claims.

Claim 10

Claim 10 depends from claim 1 and is at least patentable for reasons discussed above with respect to that claim. Additionally, claim 10 requires a patient model emulator for generating emulation force parameters. The Examiner asserts a patient model emulator is disclosed in Ella, paragraph 82. Applicant respectfully disagrees. That portion of Ella teaches that the orientation of tooth implant roots is an important parameter for a computer to consider in the design of an implant. There is nothing in the paragraph stating that the computer implements a patient model emulator and certainly there is nothing to suggest a patient model emulator that generates emulation force parameters used by a kinematic model emulator that incorporates model data in a kinematic model of a joint. For at least these reasons, claim 10 is patentable over all references of record, either alone or in combination.

Claims 11 and 12

Claims 11 and 12 depend from claim 10 and are at least patentable for reasons discussed above with respect to claims 10 and 1. Additionally, claim 11 requires the patient model emulator use data of a joint in motion for generating emulation force parameters and claim 12 requires the joint motion data be fluoroscopic data. Ella does not refer to joint motion data for a tooth implant and does not disclose the use of fluoroscopic joint motion data for emulation force parameter generation by a patient model emulator. For at least these reasons, claims 11 and 12 are patentable over all references of record, either alone or in combination.

Claim 13

Claim 13 depends from claim 12 and is at least patentable for reasons discussed above with respect to claims 12, 11, 10 and 1. Additionally, claim 13 requires the kinematic model simulator to apply emulation force parameters generated from fluoroscopic joint motion data to an implant model for a plurality of joints. None of the references of record, either alone or in combination, teach or suggest the application of such emulation force parameters by a kinematic model simulator. For at least these reasons, claim 13 is patentable over all references of record, either alone or in combination.

Claim 14

Claim 14 depends from claim 12 and is at least patentable for reasons discussed above with respect to claims 12, 11, 10 and 1. Additionally, claim 14 requires the dynamic response data analyzer to compare the dynamic response data to the fluoroscopic data used to generate the emulation force parameters to evaluate the set of model data for a plurality of joints. None of the references of record, either alone or in combination, teach or suggest the comparison of dynamic response data to fluoroscopic data used to generate emulation force parameters. For at least these reasons, claim 14 is patentable over all references of record, either alone or in combination.

Claim 15

Claim 15 depends from claim 12 and is at least patentable for reasons discussed above with respect to claims 12, 11, 10 and 1. Additionally, claim 15 requires the dynamic response data analyzer to receive data in the time domain from the kinematic model simulator. None of the references of record, either alone or in combination, teach or suggest the receipt of time domain data from a kinematic model simulator using emulation force parameters generated from fluoroscopic joint motion data. For at least these reasons, claim 15 is patentable over all references of record, either alone or in combination.

Claim 16

Claim 16 depends from claim 14 and is at least patentable for reasons discussed above with respect to claims 14, 12, 11, 10 and 1. Additionally, claim 16 requires the dynamic response data analyzer to generate a set of differential data to alter the set of model data for a plurality of joints. None of the references of record, either alone or in combination, teach or suggest the generation of differential data by a dynamic response data analyzer that compares dynamic response data to fluoroscopic joint motion data used to generate emulation force parameters. For at least these reasons, claim 16 is patentable over all references of record, either alone or in combination.

Conclusion

For the reasons set forth above, all pending claims are patentable over all references of record. Reexamination and allowance of all pending claims are earnestly solicited.

Respectfully submitted,
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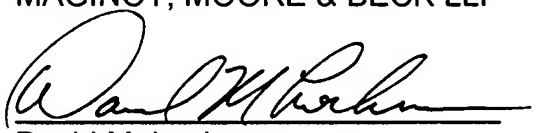

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